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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/544,776	04/07/2000	Dong Wei	59516-219/PP-01561.003	9574

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EXAMINER	
ZARA, JANE J	

ART UNIT	PAPER NUMBER
1635	

DATE MAILED: 08/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/544,776	WEI ET AL.	
	Examiner	Art Unit	
	Jane Zara	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 July 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,5-10,23-25 and 28-37* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,5-10,23-25 and 28-37* is/are rejected.

7)☒ Claim(s) *2* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This Office action is in response to the communication filed 7-29-03.

Claims 1, 2, 5-10, 23-25, 28-37 are pending in the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7-29-03 has been entered.

Response to Arguments and Amendments

Withdrawn Rejections

Any rejections not repeated in this Office action are hereby withdrawn.

Maintained Rejections/ Rejections Necessitated by Amendment

Claims 1, 5-10, 23-25, 28-37 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for the reasons of

record set forth in the Office action mailed February 26, 2001 and for the reasons set forth below.

Applicant's arguments filed 7-29-03 have been fully considered but they are not persuasive. Applicants argue that they have identified a novel human polynucleotide sequence that encodes a full length protein and believe that they are therefore entitled to the broad genus comprising a nucleic acid comprising at least 80% to the polynucleotide recited in claim 1. Applicants also argue that that the broad genera currently claimed are adequately described because the Examiner has not identified prior art precluding this claimed scope and that no legal grounds exist for an assertion that one of skill in the art could identify all polynucleotides with 95% identity, but not 80% identity. Contrary to Applicants' assertions, the written description requirement is not fulfilled by the mere absence of prior art precluding the claimed broad genera. The requirements for fulfilling written description for such broad genera claimed are elaborated in the rejection below, and rely on the ability to reasonably predict the operability of a representative number of species embraced by the genera claimed. This in turn is satisfied by concisely describing the relevant characteristics and structure/function information for the novel polypeptide and its unique activity (*e.g.* as distinguished from the other Nogo isoforms existing in the art). The disclosure of a single polypeptide sequence, along with the general description of an ER retention motif and purported membrane spanning sequences flanked by charged residues – in the absence of well developed prior art, or mutational analysis or other structure function relationships distinguishing this novel polypeptide from other endoplasmic reticulum polypeptides - do not fulfill the requirements for adequate written description for the

broad genera claimed. Applicants are correct that the assertion that one of skill in the art could identify all polynucleotides with 95% identity and not all polynucleotides with 80% identity is an arbitrary distinction. Applicants have not provided adequate written description for the genera comprising either 80% or 95% homologues of SEQ ID NO: 2 (see rejection directly below).

The claims are drawn to compositions and methods comprising polynucleotides encoding the polypeptide of SEQ ID NO: 2 or specified portions thereof (or 80% identical to these polynucleotides, wherein the polynucleotide encodes a polypeptide recognized by any antibody raised against Nogo B protein), or polynucleotides encoding this polypeptide or portions thereof, or optionally comprising between one and forty conservative amino acid substitutions, and methods of inhibiting cell growth in vitro comprising the administration of a polynucleotide between 8 and 50 nucleotides in length which is unique to Nogo B cDNA.

The specification and claims do not adequately teach or describe the broad genera claimed, which genera include polynucleotides sharing 80% identity to polynucleotides encoding SEQ ID NO: 2, wherein the polynucleotide encodes a polypeptide recognized by any antibody raised against Nogo B protein, or polynucleotides encoding any polypeptide comprising between 1 and 40 conservative amino acid substitutions of SEQ ID NO: 2. The specification and claims do not adequately describe the polynucleotides between 8 and 50 nucleobases in length that are unique to Nogo B cDNA, whereby their administration inhibits cell growth in vitro. These genera read on a myriad a different structures, and the specification and art do not describe the elements essential to the genera, whereby the distinguishing attributes

concisely shared by members of a given genus from species outside of the genus are adequately set forth.

The specification and art do not disclose other sequences, including any sequences that comprise less than 100% identity to SEQ ID NO: 2 (or a representative number of species of the genera claimed), with any activity uniquely attributed to the claimed Nogo B protein. The disclosure does not clarify what the common attributes are that encompass these broad genera. The disclosure and art do not indicate the distinguishing attributes concisely shared by the members of these genera. Thus, the scope of the claims includes numerous structural variants, and the genera are highly variant because a significant number of structural differences between members of a given genus is permitted. No common structural attributes or domains accurately identify the members of the genera claimed. The general knowledge and level of skill in the art do not supplement the omitted description because specific, not general, guidance is what is needed.

The genus comprising oligonucleotides unique to Nogo B cDNA is not adequately described. SEQ ID NO: 3, for instance (in claim 25), is considered part of the genus comprising oligonucleotides unique to Nogo B cDNA, but both Bandman (WO 98/06841) and Michalovich (WO200136631) disclose cDNA that are not Nogo B cDNA, yet which comprise sequences fully complementary to SEQ ID NO: 3 (see alignments provided with the Office action: AAV23697 is disclosed by Bandman et al and AAF90323 is disclosed by Michalovich, both of which are fully complentary to SEQ ID NO: 3). Therefore, it is unclear what concise features are encompassed by the genus

comprising the oligonucleotides between 8 and 50 nucleobases that are unique to Nogo B cDNA, and which include SEQ ID NO: 3.

In the instant situation, there is no well developed field of prior art to determine the relevant characteristics or even partial structure/function information uniquely attributed to Nogo B protein, whereby the genus comprising polynucleotides sharing 80% identity to polynucleotides encoding SEQ ID NO: 2, or polynucleotides encoding any polypeptide comprising between 1 and 40 conservative amino acid substitutions of SEQ ID NO: 2 can be precisely determined. The structure function information provided in the prior art and in the instant disclosure is of a general nature because it describes common attributes of *e.g.* endoplasmic reticular or intramembranous proteins. The presence of such common elements does not address the question of what structures are required for the broad genus comprising homologues of Nogo B, or comprising oligonucleotides unique to Nogo B cDNA. For these reasons, one of skill in the art would reasonably conclude that the disclosure and art at time of filing fail to provide a representative number of species to describe the various genera claimed. Thus, Applicant was not in possession of the broad genera claimed.

New Rejections

Specification Objection and Claim Rejections - 35 USC § 112

This application does not comply with the rules for the deposit of biological material as set forth below in the Suggestion for Deposit of Biological Material (i.e. See claim 1, line (i)). For ATCC deposits, please be sure to use the current address in Virginia, rather than the former address in Maryland.

The following is a quotation of the first paragraph of 35 USC § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and us the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to under 35 USC § 112, first paragraph as failing to provide an enabling disclosure for the claimed invention.

It is apparent that ATCC Accession No. PTA 89 is required to practice the claimed invention. As a required element it must be known and readily available to the public or obtainable by a repeatable method set forth in the specification. If it is not so obtainable or available, the enablement requirements of 35 USC § 112, first paragraph, may be satisfied by a deposit of ATCC Accession No. PTA 89. A suggestion for deposit of biological materials is provided:

A suggestion for deposit of biological materials is provided:

A declaration by applicant, assignee, or applicant's agent identifying a deposit of biological material and averring the following may be sufficient to overcome an objection or rejection based on a lack of availability of biological material. Se 37 CFR 1.801 through 1.809. Such a declaration:

1. Identifies declarant.

2. States that a deposit of the material has been made in a depository affording permanence of the deposit and ready accessibility thereto by the public if a patent is granted. The depository is to be identified by name and address.

3. States that the deposited material has been accorded a specific (recited) accession number.

4. States that all restrictions on the availability to the public of the material so deposited will be irrevocably removed upon the granting of the patent.

5. States that the material has been deposited under conditions that assure that access to the material will be available during the pendency of the patent application to tone determined by the Commissioner to be entitled thereto under 37 C.F.R. 1.14 and 35 U.S.C. § 122.

6. States that the deposited material will be maintained with all the care necessary to keep it viable and uncontaminated for a period of at least five years after the most recent request for the furnishing of a sample of the deposited microorganism, and in any case, for a period of at least thirty (30) years after the date of deposit or for the enforceable life of the patent, whichever period is longer.

7. That he/she declares further that all statements made therein of his/her own knowledge are true and that all statements made on information and belief are believed to be true; and further, that these statements were made with knowledge that willful false statements and the like so made are punishable by fine of imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the instant patent application or any patent issuing thereon.

Alternatively, it may be averred that deposited material has been accepted for deposit under the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure (e.g., see 961 OG 21, 1977) and that all restrictions on the availability to the public of the material so deposited will be irrevocable removed upon the granting of a patent.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 5-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The metes and bounds of "about 197 to about 236" (and similarly repeated for other amino residues throughout claims 1 and 5; *e.g.* see claim 1, lines 7, 8, 10-15) cannot be determined. Appropriate clarification is required.

Conclusion

Certain papers related to this application may be submitted to Art Unit 1635 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. ∋ 1.6(d)). The official fax telephone number for the Group is **703-872-9306, or after July 15, 2005, the new fax telephone number is 571-273-8300**. NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES

SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Jane Zara** whose telephone number is **(571) 272-0765.** If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang, can be reached on (571) 272-0811. Any inquiry regarding this application should be directed to the patent analyst, Katrina Turner, whose telephone number is (571) 272-0564. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jane Zara
8-9-05

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TC 1600